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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,769	01/30/2004	Nicholas V. Perricone	00961-P0146C	7069
24126	7590	10/07/2005	EXAMINER	
ST. ONGE STEWARD JOHNSTON & REENS, LLC			KIM, VICKIE Y	
986 BEDFORD STREET			ART UNIT	
STAMFORD, CT 06905-5619			PAPER NUMBER	

1618

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/768,769

Applicant(s)

PERRICONE, NICHOLAS V.

Examiner

Vickie Kim

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Response to Arguments

Obvious type- Double Patenting(DP) Rejection

Acknowledgement is made of terminal disclaimer(TD) to obviate DP rejection filed 6/27/05. The DP rejection has been withdrawn hereinafter.

102 or 103 Rejection

Applicant's arguments have been fully considered but they are not persuasive. Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

a. US6444195(COLE)

Applicant argues that US'195 fails to teach or suggest a topical composition comprising a combination of three active agents, alkanolamine, lipoic acid and tyrosine. Applicant also allegedly states that US'195 is directed to a sunscreen containing dibenzoylmethane derivative and di/polyester of naphthalene dicarboxylic acid to increase the photo-instability of dibenzoylmethane where alkanolamine, lipoic acid and tyrosine are included as adjunct agents. Applicant conclude that Cole's teaching is irrelevant to the instant claims.

Examiner disagrees.

The examiner agrees that Cole(US'195) teaches a sunscreen containing dibenzoylmethane derivative and di/polyester of naphthalene dicarboxylic acid to increase the photo-instability of dibenzoylmethane. Cole also teaches that the patented invention is incorporated into cosmetic or pharmaceutical product to enhance the efficacy of the cosmetic or pharmaceutical product which has active agents to treat certain skin conditions.

However, Cole's patent teaches a therapeutically effective composition for treating acne or other skin conditions **comprising a mixture of alkanolamine, lipoic acid and tyrosine** and a sunscreen components comprising dibenzoylmethane derivative and di/polyester of naphthalene dicarboxylic acid . Thus, Cole clearly teaches a topical composition comprising an effective amount of a mixture of alkanolamine, lipoic acid and tyrosine (0.001-20%), see claims.

Applicant's argument is not persuasive because instant claims are broadly draft where the teaching of the cited reference(US'195) embraces the scope of the claimed subject matter. Again, the claims are drawn to a **composition comprising a mixture of alkanolamine, lipoic acid and tyrosine**. Since US'195 teaches or suggests that the skin conditions(i.e acne) is effectively treated by a **composition comprising** an therapeutically effective amount of a mixture of alkanolamine, lipoic acid and tyrosine(0.001-20%), all the claimed subject matter is essentially met. Although applicant's argument is particularly emphasizing the inventive concept of US'195 patent, it is not so critical because

instant claims are not particularly drawn to a method of treating acne using only active agent consisting of a mixture of alkanolamine, lipoic acid and tyrosine.

It is noted that, the claims must be given their broadest reasonable interpretation. Therefore, the interpretation of claims (i.e. a composition comprising alkanolamine, lipoic acid and tyrosine for treating acne) should be made based on the full definition wherein the claimed subject matter is clearly taught or suggested by US'195 patent.

For the same reason, applicant's argument (i.e. Watson(US6482446) or Shapiro(US6372791) fails to teach or suggest the claimed subject matter) is not persuasive. Watson or Shapiro teaches or suggests the claimed invention where the composition of patent comprising alkanolamine, lipoic acid and tyrosine for treating skin conditions(e.g.. acne). Thus, the teaching of the cited reference renders claimed invention not obvious or not patentably distinct.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Claim Rejections - 35 USC § 102/103

Art Unit: 1618

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by, or alternatively obvious over Cole (US6444195) , Watson (US6482446) or Shapiro(US 6372791), alone.

The claims are drawn to a method of treating acne using a topical composition comprising an alkanolamine(e.g. dimethylaminoethanol, in an amount about 0.1-10%), tyrosine(0.01-6%), a sulfur-containing ingredient (e.g. lipoic acid or glutathione or mixtures thereof, 0.01-10%), or optionally salicylic acid, retinoids, ascorbic acid, etc.

Firstly, Cole(US'195, hereinafter) teaches a topical composition used in the treatment of various skin disorders such as dermatoses and erythemas, skin cancer, or skin aging and so on. US'195 further teaches the acne/wrinkle treating agents as additional active agents which are beneficially incorporated into the patented composition to enhance the therapeutic effectiveness, wherein said active agents are comprising alkanolamine(e.g. dimethylaminoethanol), lipoic acid, tyrosine, hydroxyl acids(e.g. glycolic acid), ascorbic acid derivatives, retinoic acid, salicylic acid, and said active agents are present in an amount about 0.001-20%, or mixture thereof, see col. 5, line 3 and lines 14-34 and claims 17. Therefore, the claimed feature are inherently met

where the topical application is applied, the acne will be treated naturally since acne treating active agents are added into the patented composition as set forth above.

Thus, all the critical elements required by the instant claims are well taught and the claims are anticipated by the cited reference.

Secondly, Watson(US446) or Shapiro et al(US'791) also teaches a treatment of various skin conditions using a topical composition comprising all the ingredients required by the instant claims as well.

For example, US'446 teaches improving skin conditions and treating undesirable skin conditions using topical composition comprising salicylic acid as an active agent and additionally alkanolamine(e.g. dimethylaminoethanol), lipoic acid, tyrosine, hydroxyl acids(e.g. glycolic acid), ascorbic acid derivatives and said active agents are present in an amount about 0.001-20%, or mixture thereof, see col. 3, line 65 and col. 3, lines 1-22.

US'791 also teaches a treatment for unwanted skin conditions using a topical composition comprising an alkanolamine(e.g. dimethylaminoethanol), lipoic acid, tyrosine, hydroxyl acids(e.g. glycolic acid), ascorbic acid derivatives and said active agents are present in an amount about 0.001-20%, or mixture thereof, see col. 4, lines 17-43.

Even if the claimed composition may not be included in the examples, and the weight amounts for these ingredients are not individually taught, it would have been readily apparent to any skilled artisan how to make the composition comprising such ingredients with titrating effective dosage for each active agent to maximize the

therapeutic effectiveness within the given teaching(0.001-20%). One would have been motivated to do so, with reasonable expectation of success because it is always desirable to have extended therapeutic modalities to improve patient's compliance by enhancing patient satisfaction and increasing the selection option. The techniques and skills required for making such substitution is conventional knowledge or well within the skills of ordinary artisan as evidenced by these patents cited. In order to determine best outcome, the variations including dosage regimens(e.g. interval(e.g. sequential or concurrent administration), frequency, variations in formulations or routes of administration are easily modified and considered to be minor, which does not render the claimed invention patentably distinct because the techniques and skills are routinely practiced and well known in the industry and well within the skill level of the skilled artisan.

Thus, the claims are not patentably distinct over the prior art of the record.

3. Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by, or alternatively obvious over Perricone (US 6743433, 6365623).

Because patented invention relates to a method of treating acne using the substantially same composition, the claimed invention is not patentably distinct.

For example, US'433 teaches all the critical elements(see claims) and US'623 also teaches acne treatment and the composition comprising all the ingredients required by the claims, see abstract and column 10, lines 42-50.

The claimed invention(US'623) also utilizes the composition comprising alknolamine derivatives(1-10%) such as esters of diethylaminoethanol, tyrosine(2-5%), lipoic acid(0.25-5%) , hydroxyl acid(e.g. glycolic acid, 3-7%), ascorbic acid derivatives(1-7%), salicylic acid, retinoids, etc for the treating acne and the instant claims also relates to an ane treatment using same topical composition (sequentially) requires all the said ingredients(as active agents) taught by both patents , see abstract and claims.

Thus, the scope of claimed invention of instant claims are encompassed by and thus, are not patentably distinct over the prior art of the record.

Claim Rejections - 35 USC § 102/103

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A person shall be entitled to a patent unless –

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5. Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by, or alternatively obvious over Cole (US6444195) , Watson (US6482446) or Shapiro(US 6372791), alone.

The claims are drawn to a method of treating acne using a topical composition comprising an alkanolamine(e.g. dimethylaminoethanol, in an amount about 0.1-10%),

Art Unit: 1618

tyrosine(0.01-6%), a sulfur-containing ingredient (e.g. lipoic acid or glutathione or mixtures thereof, 0.01-10%), or optionally salicylic acid, retinoids, ascorbic acid, etc.

Firstly, Cole(US'195, hereinafter) teaches a topical composition used in the treatment of various skin disorders such as dermatoses and erythemas, skin cancer, or skin aging and so on. US'195 further teaches the acne/wrinkle treating agents as additional active agents which are beneficially incorporated into the patented composition to enhance the therapeutic effectiveness, wherein said active agents are comprising alkanolamine(e.g. dimethylaminoethanol), lipoic acid, tyrosine, hydroxyl acids(e.g. glycolic acid), ascorbic acid derivatives, retinoic acid, salicylic acid, and said active agents are present in an amount about 0.001-20%, or mixture thereof, see col. 5, line 3 and lines 14-34 and claims 17. Therefore, the claimed feature are inherently met where the topical application is applied, the acne will be treated naturally since acne treating active agents are added into the patented composition as set forth above.

Thus, all the critical elements required by the instant claims are well taught and the claims are anticipated by the cited reference.

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Art Unit: 1618

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Art Unit: 1618

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The claimed invention(US'623) also utilizes the composition comprising alknolamine derivatives(1-10%) such as esters of diethylaminoethanol, tyrosine(2-5%), lipoic acid(0.25-5%) , hydroxyl acid(e.g. glycolic acid, 3-7%), ascorbic acid derivatives(1-7%), salicylic acid, retinoids, etc for the treating acne and the instant claims also relates to an ane treatment using same topical composition (sequentially) requires all the said ingredients(as active agents) taught by both patents , see abstract and claims.

Thus, the scope of claimed invention of instant claims are encompassed by and thus, are not patentably distinct over the prior art of the record.

Conclusion

1. No claim is allowed. All the pending claims 1-6 are properly maintained in the rejection above.
2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page be reached on 571-272-0602.. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 1618

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Vickie Kim', with a stylized, flowing script.

Vickie Kim
Primary Patent Examiner
October 3, 2005
Art unit 1618

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